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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,127	03/31/2004	Ashish A. Patel	G-33712P1	9219

1095 7590 08/11/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/815,127	**Applicant(s)** PATEL ET AL.	
	Examiner Kyle Purdy	**Art Unit** 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-8,10,12-16 and 18-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

/Kyle Purdy/
Examiner, Art Unit 1611
August 6, 2008

In regards to the 103(a) rejections made by the Examiner, Applicant asserts the following:
A) One would not combine the teachings of Stainforth and Uemura to reformulate MacLarens sustained release portion of their bilayer tablet.
With respect to assertion A, the Examiner respectfully disagrees. One would have been motivated to combine the teachings of MacLaren with Uemura and Stainforth with the goal of formulating a sustained release portion of MacLarens bilayer tablet. After all MacLaren does suggests the inclusion of binders, diluents, lubricants, glidants and disintegrants into the sustained portion of the bilayer composition, but specifically fails to mention weight percentages and specific compounds which fall into such categories of excipients. Stainforth and Uemura are both drawn to sustained release compositions which comprise the instantly claimed excipients for which MacLaren lacks. Such excipients include hydroxypropyl methylcellulose, lactose, carnuba wax and ethylcellulose. Therefore, one would have had a reasonable expectation for success in including such excipients because they are commonly used in sustained release tablet formulations.

The amenments which Applicant has submitted will not be entered because they were not present in the previously presented set of claims either in part (see instant claim 1) or in entirety (see instant claims 27, 30 and 31). In the case of claim 1 none of its dependent claims set forth a limitation limiting the amount of ethylcellulose to comprise from 5% to about 50% of the tablet layer. Because the limitation was not present prior to the final office action, it changes the scope of the invention which would require a new search.
The amendments pertaining to claim 27, 30 and 31 will not be entered either. Claim 27 is an independent claim. Claim 27 is directed to a bilayer tablet comprising a sustained release and an immediate release portion. This amendment will not be entered because the scope of the currently pending claim was not present in the previously presented set of claims. Because a claims possessing such limitations was not present prior to the final office action, it changes the scope of the invention and would require a new search. Claims 30 and 31 are newly added claims directed to a bilayer tablet comprising a sustained release and an immediate release portion. The amendments for these claims will not be entered because the scope of the currently pending claims were not present in the previously presented set of claims. For instance, the new claims present the sustained release portion of the tablet as comprising ethylcellulose from about 5 to about 50%, stearyl alcohol and magnesium stearate. Although these species were previously presented they were in the form of a markush grouping. Applicants narrowing of the invention narrows the scope of the invention and would require a new search.